



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,697	06/18/2002	Thomas D Reed	91830/0503228	7783
26874	7590	05/29/2008	EXAMINER	
FROST BROWN TODD, LLC 2200 PNC CENTER 201 E. FIFTH STREET CINCINNATI, OH 45202				BURKHART, MICHAEL D
ART UNIT		PAPER NUMBER		
1633				
			NOTIFICATION DATE	DELIVERY MODE
			05/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com
rgaunce@fbtlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/018,697	REED ET AL.	
	Examiner	Art Unit	
	Michael Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 2/6/2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-10 and 12-51 is/are pending in the application.
- 4a) Of the above claim(s) 38-51 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 3-10 and 12-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Receipt and entry of the amendment dated 2/6/2008 is acknowledged. After entry of the amendment, claims 1, 3-10 and 12-51 are pending. Claims 38-51 remain withdrawn as directed to a non-elected invention. Claims 1, 3-10 and 12-37 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

Claims 1, 3-10 and 12-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons made of record in the Office**

Action dated 8/27/2007, and for reasons set forth below.

Amended claim 1 (from which all other claims depend) previously recited in step d): "wherein step (d) is performed prior to, after, or concurrently with step (c)." Step d) is a step of contacting the biological sample with a chaotropic solution, and step c) is contacting the sample with a ribonuclease (e.g. RNase). Claim 1 step (d) has been amended to remove the limitation that it be performed prior to, after, or concurrently with the addition of RNase in step c), however, there are no limitations within the claim regarding order of the claimed method steps. Thus, the claims still encompass performing step (d) prior to, after, or concurrently with step c). As detailed previously ,the original claims (claim 2) and specification (page 10, lines 13-17; page

11, line 18 to page 12, line 14; and the Examples) only disclose contacting the biological sample with an RNase before contacting the sample with the chaotropic solution. Therefore, there appears to be no support for the limitations wherein step (d) of claim 1 is performed prior to, or concurrently with step (c), which are still encompassed by the claimed method. Thus, the amended claims include impermissible New Matter.

Response to Arguments

Applicant's arguments filed 2/6/2008 have been fully considered but they are not persuasive. Applicants essentially assert that claim 1 has been amended to remove the New Matter, however, as detailed above, the claims still encompass performing steps c) and d) in an order not disclosed in the specification.

Claims 29 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by amendment of the claims. This is a New Matter rejection.**

Amended claims 29 and 31 recite using detergents including "nonionic surfactants having the general formula $C_{14}H_{22}O(C_2H_4O)_n$ " (claim 29), or "a nonionic surfactant having the formula $C_{14}H_{22}O(C_2H_4O)_{7-8}$ " (claim 31). Thus, the claims have been broadened to encompass using any nonionic surfactant that might comprise the recited chemical formula (e.g. a carbon chain attached to polyethylene glycol is within the scope of the claimed formulas, and could be

considered a nonionic surfactant due to the hydrophilic nature of polyethylene glycol and the hydrophobic nature of the carbon chain). The response does not indicate where support for the amendments may be found, instead asserting that the term "Tritons" has a well-known meaning in the art as evidenced by several references (which have not been made of record, and thus not considered). A review of the specification as originally filed does not reveal disclosure of using any given nonionic surfactant with the general formulas given above. A review of the structures of two Triton compounds, X-114 and X-100, reveals a common core structure (a phenyl group bound to a polyethylene glycol chain, or PEG), see the Sigma catalog entries for Triton X-114 and Triton X-100. The Tritons differ in another group bound to the carbon opposite the PEG: an octyl group in the case of X-100, and a tetramethylbutyl group in the case of X-114. Thus, the Triton molecules are much narrower in structure than the recited chemical formulas, which do not require a phenyl or PEG group, or in the case of X-114, the tetramethyl butyl group. Thus, the scope of the claimed surfactants has been broadened to include nonionic surfactants not originally disclosed in the specification, and the amended claims include impermissible New Matter.

Claim Rejections - 35 USC § 103

Claims 1, 3-10, 12-30, and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Little (U.S. 5,075,430, 1991, of record) as evidenced by Sigma-Aldrich catalog entry for Trizma hydrochloride (2007), in view of Padhye et al (5,658,548, 1997, of record), Koller (U.S. 5,128,247, 1992) and Chomczynski (U.S. 5,945,515, 1999, effective filing date 7/31/1995). **This rejection is maintained for reasons made of record in the Office Actions dated 1/11/2005, 8/27/2007, and for reasons set forth below.**

Regarding the new limitation in step (f) of amended claim 1 that the method is substantially free of DNA binding resin or matrix, the lysis and precipitation conditions taught by Chomczynski and Koller et al do not use a DNA binding resin or matrix as set forth in the previous Office Actions. Suggestion and motivation to use such conditions in place of a DNA binding resin was also provided in the previous Office Actions, i.e. reduction in cost or time of the method because preparation or purchase of a DNA binding resin is no longer required.

Regarding the amendment to step (e) of claim 1, both Chomczynski and Koller et al teach precipitation of nucleic acids using an organic solvent for reason made of record in the previous Office Actions.

Response to Arguments

Applicant's arguments filed 2/6/2008 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Little et al does not teach using an RNase, precipitation of nucleic acids, or isolation of DNA without the use of a DNA binding material; 2) Padhye et al do not teach isolation of DNA without the use of a DNA binding material or precipitation of nucleic acids; 3) Koller et al do not teach purified extrachromosomal nucleic acids or removal of chromosomal nucleic acids; 4) Chomczynski et al do not teach purified extrachromosomal nucleic acids or removal of chromosomal nucleic acids; 5) Little and Padhye et al teach away from using a liquid based system; 6) it is unclear in the combination of the above references what process steps from Little or Padhye et al are to be replaced with Koller and Chomczynski et al, and vice versa; 7) the Examiner has not explained how the solutions of Chomczynski or Koller et al are not used as they are taught to be used, thus there would be no expectation of success upon combination with Little or Padhye et al; 8) Little and Padhye et al

are over 10+ years old, and no intervening art has taught Applicant's method; 9) Koller (1992) and Chomczynski et al (1999) fail to isolate extrachromosomal DNA, and no intervening reference between Koller and Chomczynski et al teaches the claimed invention.

Regarding 1)-5), 8) and 9), in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further regarding 5), Little and Padhye et al are silent regarding using a liquid based system, thus it is unclear how these references could teach away from such a system. Applicants do not cite or explain any passages from these references that specifically teach away from using a liquid based system.

Regarding 6), it was made clear in the previous Office Action that the lysing or nucleic acid releasing compositions and precipitation steps of Koller or Chomczynski et al could replace the chaotropic solutions and DNA resins of Little or Padhye et al (taught by Little and Padhye et al to be used after removal of extrachromosomal DNA and proteins). Given the teachings of Little and Padhye et al regarding the need to remove chromosomal nucleic acids prior to addition of a chaotropic solution or any DNA purification step in order to purify extrachromosomal DNA, it would have thus been obvious to the skilled artisan to use the teachings of Koller and Chomczynski et al as set forth by the Examiner, i.e. after the steps of Little and Padhye et al regarding cell lysis and removal of chromosomal nucleic acids. Chaotropic solutions are not used solely for the purpose of cell lysis, as suggested by applicants, rather, they are used to separate DNA from other substances and render it suitably free of contaminants and useful in

molecular biology procedures (see column 2, line 59 to column 3, line 3 and column 5, lines 46-64 of Padhye et al).

Regarding 7), the teachings of Little, Padhye, Chomczynski and Koller et al are all directed to a narrow field of nucleic acid purification and use very similar reagents and method steps. Applicants do not explain what is unpredictable about substituting one method of DNA purification for another, particularly when all the references teach the predictable use of similar reagents and method steps to arrive at a similar goal, purification of DNA. What further "knowhow" is required to follow the relatively simple recipes and steps set forth in the prior art? All of the above references are clearly enabled, as the desired products in each case were purified using readily available reagents. In light of the extensive teachings in the above references, mere substitution of one chaotropic solution lacking DNA binding resin for another that comprises such a binding resin presents no obvious technical difficulties, nor does the addition of an organic solvent in order to precipitate DNA.

Further regarding 8) and 9), in response to applicant's argument based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Little, Padhye, Koller and Chomczynski et al as applied to claims 1, 3-10, 12-30, and 32-37 above, and further in view of Colpan et al (U.S. 5,747,663, of record) as evidenced by the Sigma-Aldrich catalog entry for Triton X-114 (2008). **This rejection is maintained for reasons (in part) made of**

record in the Office Actions dated 8/27/2007, and for reasons set forth below. Amendment of the claim necessitated an additional reference

Regarding the amendment of claim 31 to recite a group of nonionic detergents having a specific formula, it is noted that Triton X-114 as taught by the Sigma catalog inherently falls within the recited formula.

Response to Arguments

Applicant's arguments filed 2/6/2008 have been fully considered but they are not persuasive. Applicants present no arguments regarding this rejection, hence, the rejection is maintained for reasons set forth above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1633

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Burkhart
Art Unit 1633

/Michael Burkhart/
Primary Examiner, Art Unit 1633